UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

DOMINIQUE BROOKS aka
DOMINIQUE REIGHARD,

Plaintiff,

v.

SANOFI-AVENTIS U.S., LLC, et al.,

Defendants.

Case No. 2:14-cv-976
JUDGE GREGORY L. FROST
Magistrate Judge Mark R. Abel

OPINION AND ORDER

This matter is before the Court for consideration of the following filings: a motion to dismiss (ECF No. 8) filed by Defendants Valeant Pharmaceuticals North America LLC, sanofi-aventis U.S. LLC, and Aventis Pharmaceuticals Inc.; a memorandum in opposition (ECF No. 19) filed by Plaintiff, Dominique Brooks; and a reply memorandum (ECF No. 24) filed by Defendants Valeant Pharmaceuticals North America LLC, sanofi-aventis U.S. LLC, and Aventis Pharmaceuticals Inc. The Court **DENIES** the motion.

I. Background

Injectable poly-L-lactic acid is classified as a prescription medical device that is used for cosmetic injections. It is sold under the trade names Sculptra and Sculptra Aesthetic. The Food and Drug Administration ("FDA") approved the former for use in treating patients with the human immunodeficiency virus ("HIV") who suffered from facial depressions or deficits. The FDA subsequently approved the latter for cosmetic use in non-HIV patients.

Beginning in August 2012 and continuing until sometime in June 2013, Plaintiff,

Dominique Brooks, received a series of prescribed injections of either Sculptra or Sculptra Aesthetic while under the care of her physician.[1] Plaintiff asserts that as a result of these injections, she suffered skin eruptions that were accompanied by serve pain, infections, oozing puss, drying of the scalp, loss of hair on her head and elsewhere on her body, injury to her nerves and nervous system, and mental anguish. She also avers that the injections caused her to develop solidified particle deposits that have necessitated removal.

In June 2014, Plaintiff filed a complaint in the Court of Common Pleas in Franklin County, Ohio, against the companies purportedly involved in developing, manufacturing, marketing, and distributing Sculptra and Sculptra Aesthetic: Valeant Pharmaceuticals North America LLC, sanofi-aventis U.S. LLC, and Aventis Pharmaceuticals Inc.[2] Defendants removed the complaint to this Court in July 2014. The complaint asserts seven state law claims: breach of warranty, manufacturing or construction defect, design or formulation defect, failure to warn or instruct, failure to conform to a representation, supplier liability, and negligence and vicarious liability. (ECF No. 5 ¶¶ 11-55.) Following removal, Defendants filed a motion to dismiss all of these claims. (ECF No. 8.) The parties have completed briefing on the motion, which is ripe for disposition.

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[1] Given the uncertainty over which particular product Plaintiff received, the Court shall refer to Sculptra and Sculptra Aesthetic as simply "Sculptra" herein unless context necessitates greater specificity.

[2] Although the complaint also names John Does # 1-25, the Court shall use "Defendants" to refer to the movant companies: Valeant Pharmaceuticals North America LLC, sanofi-aventis U.S. LLC, and Aventis Pharmaceuticals Inc., all of which are identified herein by the company names they use in their briefing and not by the apparently slightly incorrect designations contained in the complaint.

II. Discussion

A. Standard Involved

Defendants move for dismissal on the grounds that Plaintiff has failed to assert claims upon which this Court can grant relief. This Federal Rule of Civil Procedure 12(b)(6) argument requires the Court to construe the complaint in Plaintiff's favor, accept the factual allegations contained in that pleading as true, and determine whether the factual allegations present any plausible claim. *See Bell Atlantic Corp. v. Twombly*, 550 U.S. 554, 570 (2007). The United States Supreme Court has explained, however, that "the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Thus, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id.* Consequently, "[d]etermining whether a complaint states a plausible claim for relief will . . . be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

To be considered plausible, a claim must be more than merely conceivable. *Twombly*, 550 U.S. at 556; *Ass'n of Cleveland Fire Fighters v. City of Cleveland, Ohio*, 502 F.3d 545, 548 (6th Cir. 2007). What this means is that "[a] claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. The factual allegations of a pleading "must be enough to raise a right to relief above the speculative level . . . ." *Twombly*, 550 U.S. at 555. *See also Sensations, Inc. v. City of Grand Rapids*, 526 F.3d 291, 295 (6th Cir. 2008).

B. Analysis

Despite the briefing, Defendants' argument for dismissal is simple: federal law preempts Plaintiff's state law claims.[3] Defendants explain that, as a Class III medical device, Sculptra went through the FDA's Premarket Approval ("PMA") process. Because Plaintiff's state law claims would impose requirements that do not mirror the requirements created by the PMA process, Defendants reason, a statutory preemption clause applies and entitles them to dismissal with prejudice. Plaintiff of course disagrees on the ground that her claims fall outside the scope of the statutory preemption provision.

In addressing the PMA process, the United States Supreme Court has explained that "the FDA requires a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008). A consequence of this rationale and the

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[3] Two points are warranted. First, much of the parties' briefing is not relevant to the core issue presented by the motion to dismiss, and the parties' mutual attempts to rely on material extrinsic to the complaint is unhelpful. Rather, the face of the complaint presents all that is needed to resolve the issue of preemption at this juncture in the case.

Second, in a footnote in their reply memorandum, Defendants contend that Plaintiff has conceded various arguments for dismissal that are independent from the federal preemption argument. (ECF No. 24, at Page ID # 309 n.7.) The reply memorandum footnote then directs this Court to three footnotes contained in the memorandum in support of Defendant's motion to dismiss, each of which contains one or more one- to two-sentence arguments for dismissal with string citations. *See* ECF No. 8, at Page ID # 128 n.6, Page ID # 133 n.7, Page ID # 134 n.8. This essentially perfunctory method of briefing fails to constitute developed arguments that this Court will consider adequately presented for disposition. *See Embassy Realty Investments, Inc. v. City of Cleveland*, 976 F. Supp. 2d 931, 944 (N.D. Ohio 2013) (rejecting an argument presented "in the most skeletal way, leaving the court to . . . put flesh on its bones"); *cf. Kuhn v. Washtenaw Cnty..*, 709 F.3d 612, 624 (6th Cir. 2013) (declining to consider arguments briefed in only a perfunctory manner). The Court expresses no opinion on the merits of these potential arguments, which Defendants may raise in a future motion.

statutory scheme presented by the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act is that the MDA expressly preempts state claims that impose requirements that are different from, or in addition to, these federal requirements. *Riegel*, 552 U.S. at 321; *see also* 21 U.S.C. § 360(k)(a).

Plaintiff argues that dismissal is not appropriate because her claims fall outside the scope of the MDA's preemption clause. This is possible. The Supreme Court noted in *Riegel* that "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. 552 at 330 (quoting 21 U.S.C. § 360(k)(a)(1)). Thus, parallel state claims–claims premised on a violation of an FDA requirement–indeed evade preemption. *Id.* Plaintiff therefore characterizes Defendants' motion as premature and asks this Court to permit discovery that would enable her to provide a detailed statement of the specific bases for her claims–in other words, to uncover the facts that would enable her to assert that her claims parallel to the federal requirements.

Some courts follow this approach. For example, in *Bausch v. Stryker Corp.*, 630 F.3d 546 (7th Cir. 2010), the Seventh Circuit Court of Appeals addressed the problem of how to plead in Class III medical device cases in light of the plausibility standard of *Iqbal* and *Twombly*. The Seventh Circuit explained:

> In applying that standard to claims for defective manufacture of a medical device in violation of federal law, moreover, district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law. Formal discovery is necessary before a plaintiff can fairly be expected to provide a detailed statement of the specific bases for her claim.

Id. at 558. Accordingly, the court of appeals concluded that a district court had erred by dismissing a plaintiff's original complaint and by denying that plaintiff leave to file an amend

complaint. *Id.* Notably, the Court reasoned as follows:

> Defendants object that the original complaint does not specify the precise defect or the specific federal regulatory requirements that were allegedly violated. Although the complaint would be stronger with such detail, we do not believe the absence of those details shows a failure to comply with Rule 8 of the Federal Rules of Civil Procedure or can support a dismissal under Rule 12(b)(6). First, Rule 9(b) does not impose any special requirement that such a claim be pled with particularity, as it does for fraud claims, for example.
>
> Second, the victim of a genuinely defective product . . . may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem. . . .
>
> Third, in the context of Class III medical devices, much of the critical information is kept confidential as a matter of federal law. The specifications of the FDA's premarket approval documents, for example, are confidential, and there is no public access to complete versions of these documents. An injured patient cannot gain access to that information without discovery. See 21 C.F.R. § 814.9; *Medtronic Leads*, 623 F.3d at 1211 n.7 (Melloy, J., dissenting). If the problem turns out to be a design feature that the FDA approved, section 360k will protect the manufacturer. *Riegel*, 552 U.S. at 330, 128 S.Ct. 999. But if the problem turns out to be a failure to comply with the FDA's legally enforceable conditions for approval of the device, section 360k will not protect the manufacturer.
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> . . . [O]ne of the only two other circuits to examine the application of *Riegel* to medical device preemption is the Eighth Circuit in *Medtronic Leads*, where the majority concluded that the plaintiffs had waived discovery early in the proceedings. The majority upheld the district court's refusal to grant the plaintiffs discovery to respond to the motion to dismiss. There the court acknowledged the plaintiffs' argument that the district court held them to an "impossible pleading standard" because the FDA's premarket approval application was accessible only to the FDA and the manufacturer. The court found that "this argument—which focuses on the timing of the preemption ruling—would have considerable force in a case where a specific defective Class III device injured a consumer, and the plaintiff did not have access to the specific federal requirements in the [premarket approval application] prior to commencing the lawsuit." *Medtronic Leads*, 623 F.3d at 1206. That is exactly the situation in this case. Here, there has not yet been an opportunity for discovery, and Bausch never waived discovery. For her to plead with any more detail that her claims were "based entirely on a specific defect in the Trident that existed outside the knowledge and regulations of the FDA," she would need access to the confidential materials in the premarket approval application setting forth the medical device's specifications. This is simply not possible without discovery. It

> is also unreasonable to expect that Bausch could have pled more specifically without access to the failed Trident itself, but accessing the Trident outside of a discovery process would risk charges of spoliation of evidence, as Bausch's counsel acknowledged at oral argument. As Judge Melloy noted in *Medtronic Leads*: "If plaintiffs must allege that the defendant violated a particular FDA-approved specification before discovery, then it is difficult to appreciate how any plaintiff will ever be able to defeat a Rule 12(b)(6) motion." *Id.* at 1212 (Melloy, J., dissenting). We think Judge Melloy said it well in suggesting that, in analyzing the sufficiency of pleadings, "a plaintiff's pleading burden should be commensurate with the amount of information available to them." *Id.*

Id. at 560-61.

Bausch makes sense to this Court. Defendants seek to distinguish that case on grounds that are inconsequential to its core rationale. The point is that the Seventh Circuit's measured approach logically avoids the harsh result seen in those cases that find preemption based only on notice pleading. It would impose an illogical pleading burden on Plaintiff to require her complaint to point to specific federal requirements in order to establish that her state law claims are parallel and thus not preempted. It also would require too much to demand that Plaintiff allege specific defects that violate the FDA standards when such information is not necessarily within her control.

Discovery would thus afford Plaintiff the fair opportunity to evade preemption if such evasion is warranted, and, as Plaintiff concedes, summary judgment affords Defendants the mechanism through which they might ultimately prevail in this lawsuit if preemption applies. To decide the issue against Plaintiff here on the understandably limited context of an initial complaint would perhaps not only require more than Plaintiff could reasonably be expected to give, but also would impose more stringent requirements than notice pleading under Federal Rule of Civil Procedure 8 demands. Therefore, even setting aside the parties' various debates over issues such as off-label use, dismissal is not appropriate at this time on the parallel claim

basis.

III. Conclusion

The Court **DENIES** the motion to dismiss. (ECF No. 8.)

IT IS SO ORDERED.

/s/ Gregory L. Frost
GREGORY L. FROST
UNITED STATES DISTRICT JUDGE